Amendment #2

to RFP-NIH-NIAID-DMID-05-12

“Animal Models for the Prevention and Treatment of Hepatitis B and Hepatitis C"

Amendment to Solicitation No.:	**NIH-NIAID-DMID-05-12**
Amendment No.:	**2**
Amendment Date:	**November 23, 2004**
RFP Issue Date:	**September 30, 2004**
Proposal Due Date:	**January 05, 2005 (unchanged)**
Issued By:	**Paul D. McFarlane Contracting Officer DHHS/NIH/NIAID Contract Management Program 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, Maryland 20892-7612**
Point of Contact:	**Yvette R. Brown, Contract Specialist 301-451-3686 vbrown@niaid.nih.gov**
Name and Address of Offeror:	**To All Offerors**

The hour and date for receipt of the offeror HAS NOT BEEN EXTENDED. Offerors shall acknowledge receipt of this amendment by noting, on the face page of the original technical and business proposal, that the offer has been prepared in accordance with the original solicitation and all its amendments. Failure of the offeror to submit this acknowledgement may result in the rejection of your offer. Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full force and effect.

Purpose of Amendment: To replace Section M of the RFP.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

The major evaluation factors for this solicitation include technical (which encompasses experience and past performance factors) cost/price factors and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that Offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractor in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below. Proposals will be judged solely on the written material provided by the Offeror. Failure to provide the information required to evaluate the proposal may result in rejection of that proposal without further consideration.

NIAID may establish separate Scientific Review Groups to evaluate proposals for hepatitis B and hepatitis C.

2. MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria. THE OFFEROR SHALL INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS PROPOSAL.

The qualification criteria establish conditions that must be met at the time of submission of the Technical Proposal in order for your proposal to be considered for award.

The Offeror shall demonstrate the availability of a small mammalian viral hepatitis model and all laboratory facilities necessary to perform the tasks set forth in the Statement of Work. This includes continuous daily access to an AAALAC-accredited (or equivalent for non-US institutions) animal facility throughout the Contract period. The vivarium shall be approved for housing either an HBV model or HCV model or a comparable surrogate virus model of HBV or HCV.

3. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy. If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

4. EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH

The offeror's proposal must address the plans for sharing model organisms. OR state appropriate reasons why such sharing is restricted or not possible. Offerors must also address as part of the sharing plan if, or how, they will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. The discussion areas regarding intellectual property outlined in Section L should be addressed.

If your proposal does not include a plan, appropriate reasons for restricting sharing, or, if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan for sharing model organisms during discussions and in your Final Proposal Revision (FPR). If your plan for sharing model organisms is still considered "unacceptable," or your justification for restricting sharing is still considered inappropriate by the Government after discussions, your proposal may not be considered further for award. Examples of sharing plans can be found at the following address: http://grants.nih.gov/grants/policy/model_organism/index

5. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the Technical Evaluation Committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes. Proposals will be judged solely on the written proposals and materials provided by the Offerors.

1. <u>Technical Approach</u>—listed in descending order of importance **65**

METHODS, STUDY DESIGNS & ANALYSES: (35 points)

Completeness and rigor of the "proof-of-concept" efficacy study of a licensed therapy tested in the animal model to include critical and incisive analysis of the data, proper use of controls, and optimal use of available tools to reach the final conclusion

Adequacy and feasibility of the methods proposed to measure outcomes, including sensitivity, specificity, dynamic range, and reproducibility of: 1) viral assays (nucleic acids, antigens and antibodies in sera and liver), 2) liver injury and disease progression, 3) gross pathology and histopathology, and 4) safety/toxicity

Adequacy and feasibility of the sample protocols and methods of data analysis for (1) combinations of therapeutics, (2) vaccine study, or (3) dosing and collecting samples for pharmacologic studies.

Adequacy of standard operating procedures (SOPS) for the safety and welfare of personnel and animals.

ANIMAL MODEL: (30 points)

Suitability, feasibility, reproducibility and availability of the animal model(s) for the evaluation of broadly different classes of therapeutics and/or vaccines, and predictability of the test results on future clinical responses by patients

Adequacy of the animal model to imitate important aspects of the human infection including similar host immune responses to infection and treatment

Adequacy of an HCV animal model to assess protection by a candidate vaccine.

2. <u>Personnel</u> **25**

A. PROFESSIONAL PERSONNEL: (15 points)

Adequacy and appropriateness of the training, expertise, experience, availability and
capability of the Principal Investigator in conducting and managing an integrated
project as well as planning and conducting animal model protocols. Expertise and
experience of the Principal Investigator and the team of professional personnel in:
characterizing, developing and maintaining a hepatitis B or hepatitis C animal model;
protocol design for the *in vivo* evaluations of therapeutics or vaccines;
the design, use and analysis of assays and diagnostics;
accountability for all phases of project management including preparation of deliverables and reports; and
optimized production and care of animals.

B. TECHNICAL SUPPORT PERSONNEL: (10 points)

Adequacy and appropriateness of training, education, and experience of the technical personnel to:
provide routine and special care for the animals;
perform the variety of required animal protocols and associated clinical procedures;
conduct laboratory assays, techniques and;
handle infectious agents.

3. Resources and Administration: 10

Adequacy and feasibility of the infrastructure for the Offeror to coordinate and administer the multiple aspects of the proposed contract as evidenced by:

a. Quality and safety of facilities including lab space to conduct proposed research and prevent unintended spread of infectious agents;
In place procedures and practices to ensure rapid communication, report dissemination, and coordination of activities;
Electronic tracking of animal specimens both stored and sent;
Capacity to safeguard, manage, enter, exchange, analyze, and communicate data; and
Standard operating procedures in place for monitoring personnel health with respect to infectious agents.

Total Possible Points **100**

6. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent of commitment to use SDB concerns
(b) Realism of the proposal
(c) Extent of participation of SDB concerns in terms of the value of the total acquisition

END OF AMENDMENT 2 TO RFP NIH-NIAID-DMID-05-12